

Pharmaceutical Quality Systems

An updated approach to Quality System Management

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Pharmaceutical Quality Systems

FDA Report

“Pharmaceutical cGMPs for the 21st Century – a risk based approach”.

September 2004

www.fda.gov/Cder/gmp/gmp2004/GMP_finalreport2004.htm



Pharmaceutical Quality Systems

Q10 Pharmaceutical Quality Systems

Facilitate:

- Q8 Pharmaceutical development
- Q9 Quality risk management



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Q8 Pharmaceutical development

Quality by design (QbD):

- Product
- Process



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Q8 Pharmaceutical development

Change control:

- Support of design space definition
- Opportunities to improve

Design space:

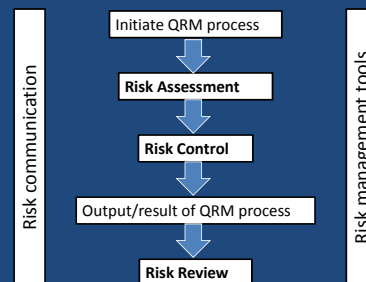
“The multidimensional combination and interaction of material attributes and process parameters that have been demonstrated to provide assurance of quality”

ICH Q8



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Q9 Quality risk management



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Objectives:

- Achieve product realisation
- Establish & maintain a state of control
- Facilitate continual improvement



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Elements:

- Process performance & product quality monitoring system
- CAPA system
- Change management system
- Management review



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Structure:

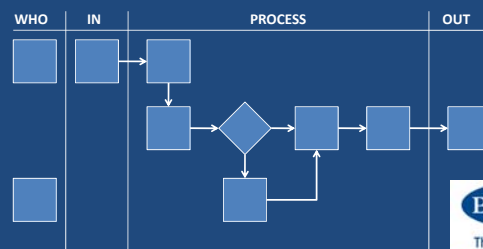
- Quality Policy
- Quality Objectives
- Quality Planning
- Processes
- Continual improvement



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Process understanding:



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Regulatory control:

- QbD
- QRM
- Risk based



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Potential benefits:

- Ongoing improvements in performance
- Reduction in cost of internal failures
- Reduction in the costs of preparing/reviewing certain regulatory submissions
- Enhanced assurance of the quality of medicines available to patients



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Independent research:

- Improved performance of a process yields a 1000 fold greater decrease in defect rates than increasing QC
- A decrease in internal failure costs could reduce the cost of goods by up to 3%
- For the top 30 pharmaceutical companies this could yield annual savings in excess of €8 billion

"The Metamorphosis of Manufacturing from Art to Science"
IBM Business Consulting May 2005



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